K043175

NOV 2 4 2004

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
(317) 521-3544

Contact Person: Kay A. Taylor

Device Name

Proprietary name: Elecsys® Cortisol Immunoassay System

Common name: Cortisol Test

Classification name: Fluorometic, cortisol

Device Description

The Elecsys Cortisol Assay is a two step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection. Results are determined using a calibration curve that is generated specifically on each instrument by a 2 point calibration and a master curve provided with the reagent bar code.

Intended use

For the in vitro quantitative determination of cortisol in human serum, plasma, urine and saliva.

Note: Serum and plasma cleared under K000270 and urine cleared under K021218.

Indications for Use

The determination of cortisol is used for the recognition and treatment of functional disorders of the adrenal gland.

510(k) Summary, Continued

Substantial equivalence

The Elecsys Cortisol Immunoassay is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the Salimetrics HS (high sensitivity) Salivary Cortisol Enzyme cleared under K011323. Both products are intended for use in the quantitative determination of cortisol in human saliva.

Substantial equivalence - comparison

The following table compares the Roche Elecsys Cortisol Immunoassay with the predicate device.

Feature	Elecsys Cortisol Immunoassay	HS Salivary Cortisol Enzyme (predicate)
Intended Use	For the in-vitro quantitative determination of cortisol in serum, plasma, urine and saliva.	For the in vitro quantitative determination of cortisol in saliva.
Indication for Use	The determination of cortisol is used for the recognition and treatment of functional disorders of the adrenal gland.	Used to measure adrenal cortical function and as a screen for Cushing's and Addison's disease. Saliva cortisol accurately reflects the amount of serum cortisol in the circulation.
Assay Protocol	Electrochemiluminescent Immunoassay	Competitive Solid Phase Immunoassay
Traceability / Standardization	Enzymun Test Cortisol, in turn standardized via ID-MS.	N/A
Calibration Interval	E170/E2010 • After 1 month when using the same reagent lot • After 7 days when using the same reagent kit E1010 • With every reagent kit • After 7 days (20-25°C) • After 3 days (25-32°C)	N/A
Sample Type	Serum, plasma, urine & saliva	Saliva

Feature	Elecsys Cortisol Immunoassay	HS Salivary Cortisol Enzyme (predicate)
Sample Collection Method	Salivettes (Sarstedt)	Salivettes (Sarstedt)
Reagent Stability	Unopened at 2-8°C • Up to stated expiration Opened • 12 weeks at 2-8° • 8 weeks on E170/ 2010 • 2 weeks on E1010 (20-25° ambient temp - up to 20 hours opened in total)	Stable at 2-82-8°C until kit expiration date
Controls	Elecsys PreciControl Universal 1 and 2	Cortisol Controls
Calibrator	Elecsys Cortisol CalSet	Cortisol Standards
Measuring Range	1.00 - 1750 nmol/L (0.036 - 63 ug/dL)	Calibrator range 0.007-1.800 ug/dl
Instrument	Elecsys family of analyzers (Elecsys 1010, Elecsys 2010 and Elecsys E170 MODULAR Analytics Immunoassay Analyzers)	Standard plate reader

Expected Values	Morning hours 8-10 AM: 1.90 – 19.1 nmol/L Afternoon hours 2:30-3:30 PM: 2.05 – 11.9 nmol/L	**Neonatal** 0.010 – 3.606 ug/dl **Age 6 months** 0.010– 2.890 ug/dl **Age 2.5-5.5 years** AM: 0.060-0.700 ug/dl PM: 0.08-0.660 ug/dl **Age 8-11 years** AM: 0.112-0.904 ug/dl PM: ND – 0.249 ug/dl **Age 12-18 years** AM: 0.046-0.950 ug/dl PM: ND-0.296 ug/dl **Age 21-30 years, males** AM: 0.112-0.743 ug/dl PM: ND-0.308 ug/dl **Age 21-30 years, females** AM: 0.272-1.348 ug/dl PM: ND-0.359 ug/dl **Age 31-50 years, males** AM: 0.122-1.551 ug/dl PM: ND – 0.359 ug/dl **Age 31-50 years, females** AM: 0.094-1.515 ug/dl PM: ND-0.181 ug/dl **Age 51-70 years, males** AM: 0.112-0.812 ug/dl PM: ND – 0.228 ug/dl **Age 51-70 years, females** AM: 0.149-0.739 ug/dl PM: 0.022-0.254 ug/dl **All Adults** AM: 0.094-1.551 ug/dl PM: ND-0.359 ug/dl ND=none detected Normal 0.004-0.116 ug/dl Cushing's 0.141-9.170 ug/dl

510(k) Summary, Continued

Substantial equivalence – performance characteristics

The performance characteristics of the Elecsys Cortisol Immunoassay and the predicate device are compared in the table below.

Feature	Elecsys Cortisol Immunoassay	HS Salivary Cortisol Enzyme (predicate)
Precision	E2010 Within-run 6.1% CV @ 0.170 ug/dL 2.7% CV @ 0.417 ug/dL 4.0% CV @ 0.547 ug/dL 1.5% CV @ 0.576 ug/dL 2.8% CV @ 0.718 ug/dL Between Run *37.1% CV @ 0.034 ug/dL 7.2% CV @ 0.280 ug/dL 6.2% CV @ 0.613 ug/dL 4.9% CV @ 1.25 ug/dL 4.1% CV @ 1.54 ug/dL *sample concentration below functional claim of assay.	Intra-assay 4.25% CV @ 1.591 ug/dL 4.97% CV @ 0.702 ug/dL 5.73% CV @ 0.188 ug/dL 5.28% CV @ 0.115 ug/dL
Functional Sensitivity	< 2.0 nmol/L (< 0.07 ug/dL)	N/A
Analytical sensitivity (LDL)	< 0.500 nmoL/L (< 0.018 ug/dL)	< 0.007ug/dL
Method Comparison	Elecsys Cortisol vs. Salimetrics 326 samples (0.05-1.83 ug/dl) Slope = 0.90 (95% CI 0.87-0.94) Intercept= 1.71 (95% CI 1.47-1.96) r= 0.942	N/A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 4 2004

Kay A. Taylor, MT (ASCP), RAC
Regulatory Program Principal, Regulatory Affairs
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k043175
Trade/Device Name: Elecsys Cortisol
Regulation Number: 21 CFR 862.1205
Regulation Name: Coristol (hydrocortisone and hydroxycorticosterone) Test System
Regulatory Class: Class II
Product Code: NHG
Dated: November 9, 2004
Received: November 16, 2004

Dear Ms. Taylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K043175**

Device Name: **Elecsys Cortisol**

Indications For Use:

The Elecsys Cortisol is an immunoassay for the in-vitro quantitative determination of cortisol in serum, plasma, urine and saliva.

The determination of cortisol is used for the recognition and treatment of functional disorders of the adrenal gland.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys 1010/2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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